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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,466	07/29/2003	Anandan Palani	IN01481KB	7306
24265 7590 06/20/2007 SCHERING-PLOUGH CORPORATION PATENT DEPARTMENT (K-6-1, 1990) 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033-0530			EXAMINER CHANG, CELIA C	
			ART UNIT 1625	PAPER NUMBER
			MAIL DATE 06/20/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/629,466

Applicant(s)

PALANI ET AL.

Examiner

Celia Chang

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

1. This is a RCE of SN 10/629,466.

The amendment filed on April 6, 2007 have been entered and considered carefully.

Claims 1-20, 31-40 have been canceled. Claims 22-30 are pending.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Albert et al. US 2004/0142920, supplemented with the GB application 0108876.4.

Determination of the scope and content of the prior art (MPEP §2141.01)

Albert et al. '920 has an effective filing date of April 9, 2001 (see priority documents for WO 02/081449). , the scope wherein R2 is 6-membered heteroaryl group has been disclosed and is entitled to the priority date of Aug. 9, 2001. An example of the claimed compound was found on page 5 of the priority document wherein R2 is phenyl. Generically, the R2 being phenyl or 6-membered heteroaryl which is selected from pyridyl, pyrimidyl or pyridazinyl were taught to be optional choices for the R2 moiety (see page 3, line 3).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the elected species and Albert et al.'920 reference is that when R3 is dimethylpyrimidinyl moiety, instead of both R1 and R2 are optionally substituted phenyl, while the instantly elected species has one of the R2 moiety being benzyl. Or, when one of R1 or R2 is benzyl, the R3 moiety is dimethylphenyl. Generically, Albert et al. '920 taught that R2 being phenyl or benzyl, or R3 being dimethylphenyl or dimethyl pyrimidyl, are optional choices for such moiety (see p.5, example 9 or p. 10, example 53).

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Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)

One having ordinary skill in the art would be motivated to modify the species of the elected compound with the generically taught optionally choices of equivalency in replacing the phenyl moiety with a benzyl moiety or dimethylphenyl moiety with a dimethylpyrimidyl moiety with the expectation that such modification would render the modified compound having similar biological activity.

Applicants provided a declaration under 37 CFR 1.132 dated Mar. 8, 2007. Please note that only compound example 9 on page 2 corresponds to the instantly elected scope. The comparative reference compound differ from the compound example 9 is not a vis-à-vis comparison since multiple differences in phenyl vs benzyl and dimethylphenyl vs dimethylpyrimidyl existed. Please note the above delineation of species which differ from the compound example 9 by only one structural feature. In addition, mere differences in binding property among different compounds is *expected*. To show unexpectancy, a clear showing of similarity with equivalent Markush groups with the compared structural feature distinct from such similarity in statistical significant factual evidence must be presented.

3. Claims 21-22, 24-26, 29-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

On page 11 of the specification the term “solvate” is described as:

*“Prodrugs and solvates of the compounds of the invention are also contemplated within the scope of this invention. The term “prodrug”, as employed herein, denotes a compound that is a drug precursor which, upon administration to a subject, undergoes chemical conversion by metabolic or chemical processes to yield a compound of formula I or a salt and/or solvate thereof.”*

It is very confusing as to what and how the salts or solvates were made. Only metabolically? In addition while acid addition salts can be conventionally made after synthesis of an organic amine containing compound, the making and obtaining of “solvates” must be independently described and enabled since solvates are separate chemical identity and there is no standard operability in which and how solvates can be made (see Braga et al. p.3640). Absent of any description of what kind of solvent will form solvates, and how and what solvates were made, the specification provided no enablement to the scope of the claims.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Jun 12, 2007



Celia Chang  
Primary Examiner  
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